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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,711	01/12/2004	Deborah Kim Glencross	025455-113	1340

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BUCHANAN, INGERSOLL & ROONEY PC  
POST OFFICE BOX 1404  
ALEXANDRIA, VA 22313-1404

EXAMINER

FORD, ALLISON M

ART UNIT	PAPER NUMBER
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1651

NOTIFICATION DATE	DELIVERY MODE
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10/11/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

Application No.

10/754,711

Applicant(s)

GLENCROSS, DEBORAH KIM

Examiner

Allison M. Ford

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4 and 6-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 14 and 16 is/are rejected.
- 7) ☒ Claim(s) 1, 2, 5 and 14-16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response of 10 July 2007 has been received and entered into the application file. Claims 1, 2 and 15 have been amended; claims 1-16 remain pending in the current application, of which claims 3, 4 and 6-13 are withdrawn from consideration as being directed to non-elected subject matter. Claims 1, 2, 5 and 14-16 have been considered on the merits. All arguments have been fully considered.

#### ***Priority***

Acknowledgment is made of applicant's claim for priority as a continuation of PCT/IB/02/02725 filed on 11 July 2002, which further claims priority to South African national application 2001/5700, filed on 11 July 2001.

#### ***Claim Objections***

Claim 1 is objected to because the term "CD4 Bright low side scatter" (lines 14-15 of claim 1) should be written "CD4<sup>Bright</sup>/low side scatter". Correction is required. Claims 2, 5, and 14-16 inherit this deficiency.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2, 14 and 16 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is rejected for failing to properly correlate to the steps of the parent claim (claim 1), as follows:

First, claim 1 no longer recites “white blood cells” but now refers to CD45+ cells; therefore claim 2 technically lacks antecedent basis for the limitation “the white blood cells counted...” in lines 3 and 6 of the claim.

Second, claim 1 now requires step (b) determining the proportion of CD45+ cells which are CD4+ lymphocytes to be carried out via flow cytometry; therefore, second alternative in claim 2, “or whereby the number of white blood cells counted in step (a) is obtained on a hematology analyzer and the proportion or percentage of CD4+ lymphocytes determined in step (b) is also performed on a hematology analyzer” contradicts the method outlined in claim 1. Cancellation of this second alternative is required in order to properly correlate with claim 1.

For claim 2, the following claim language is suggested:

*“Claim 2. The method according to claim 1, wherein step (a) determining the absolute number of CD45+ cells in the cell sample is performed via flow cytometry using a bead-based or volumetric-based counting method.”*

Claim 14 is rejected as it fails to specifically define what cell population is being considered for the “absolute cell count”. It should refer to the absolute CD45+ cell count.

For claim 14, the following claim language is suggested:

*“Claim 14. The method according to claim 2, wherein the bead-based counting method comprises adding a known number of beads to the cell sample; and counting the beads and cells simultaneously to obtain the absolute CD45+ cell count.”*

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Claim 16 stands rejected because it remains indefinite in light of the amendments to claim 1.

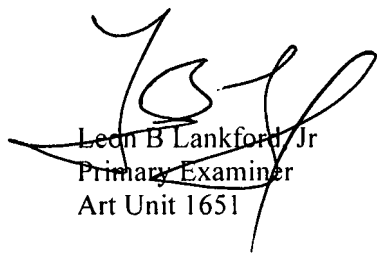
Claim 1 no longer involves a step of determining the number of white blood cells per volume of blood in step (c).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leon B Lankford Jr  
Primary Examiner  
Art Unit 1651